Utilization and Tolerability of Anifrolumab-fnia in Home Infusion Patients

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Background

Systemic lupus erythematosus (SLE) is the most common form of lupus, a chronic autoimmune disorder where the immune system attacks healthy tissues and cells causing inflammation and damage across various organs, including the skin, joints, kidneys, and brain. Anifrolumab-fnia (Saphnelo) was approved by the FDA in 2021 for the treatment of SLE, as an addition to standard therapy. The American College of Rheumatology Lupus Clinical Practice is estimated to be released in spring of 2025. However, the 2023 update to the European Alliance of Associations for Rheumatology (EULAR) guidelines recommend belimumab and anifrolumab as first line therapy in severe cases of SLE with non-major organ development.[1]

Anifrolumab-fnia is a monoclonal antibody that targets and inhibits the type I interferon receptor (IFNAR). Type I interferons are over-produced in SLE, driving inflammation and immune dysregulation. By blocking this receptor, anifrolumab-fnia reduces inflammatory responses, thereby alleviating SLE symptoms and limiting organ damage. Clinical trials have demonstrated that administering anifrolumab-fnia at 300 mg every four weeks effectively lowers overall lupus disease activity, improves skin and join symptoms, and allows for reduced steroid use.

Unlike existing SLE treatments such as hydroxychloroquine, systemic glucocorticosteroids, and belimumab *(Table 1)*, which may leave residual symptoms, anifrolumab-fnia offers a distinct advantage by targeting all type I interferon receptors without requiring a loading dose, reconstitution, or lab monitoring. This makes it a promising option for enhancing SLE management.

Purpose

The primary objective of this study is to assess the usage of anifrolumab-fnia for SLE in home infusion patients. The secondary objective is to assess patient tolerability of anifrolumab-fnia.

Methods

This was a retrospective, multi-center study including patients who were initiated on anifrolumab-fnia over a period of 3 years. Data collection included prior medication history, usage of steroids, concomitant medications for SLE, and tolerability. Data was collected through electronic medical records. Research is IRB exempt.

References

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Table 1: Guideline Treatment for SLE

Medication	Mechanism of Action (MOA)	Benefits in Treating Lupus
Belimumab	Inhibits **BLyS** to reduce B-cell survival and autoantibody production[2]	Reduces flares, improves fatigue, effective in **autoantibody-positive** lupus
Hydroxychloroquine	Increases **lysosomal pH**, reducing antigen presentation and immune activation[3]	Decreases flares, protects against organ damage, lowers risk of lupus nephritis, well-tolerated long-term
Methotrexate	Inhibits **dihydrofolate reductase**, suppressing T and B-cell proliferation [4]	Effective for **arthritis** and **skin manifestations**, helps reduce steroid use
Mycophenolate	Inhibits **IMPDH**, selectively affecting B and T cells [5]	First-line for **lupus nephritis**, controls systemic and skin involvement, better side effect profile than cyclophosphamide
Azathioprine	Inhibits **purine synthesis**, leading to decreased immune cell proliferation [6]	Steroid-sparing agent, useful in **lupus nephritis**, suitable for long-term use
Leflunomide	Inhibits **dihydroorotate dehydrogenase**, reducing T-cell proliferation [7]	Effective for **lupus arthritis**, alternative to methotrexate
Rituximab	Targets **CD20** on B cells, leading to B-cell depletion [8]	Useful for **refractory lupus** and **severe lupus nephritis**, reduces autoantibody production
Cyclophosphamide	Alkylates DNA, preventing immune cell replication [9]	Reserved for **severe lupus** (e.g., nephritis, CNS lupus), effective but highly toxic
Abatacept	Inhibits **T-cell activation** by blocking the CD80/CD86 co-stimulatory signal [10]	May reduce **joint inflammation**, useful in lupus arthritis
Quinacrine	Immunomodulatory action similar to hydroxychloroquine (exact MOA unclear) [11]	Beneficial for **cutaneous lupus** and mild systemic disease, often combined with hydroxychloroquine

Figure 1: Discontinuation Reasons

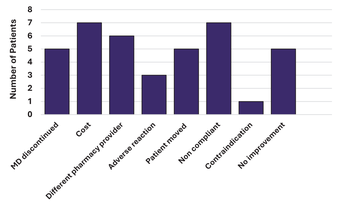

Figure 2: Previous Medications for Lupus in Patients Who Discontinued anifrolumab

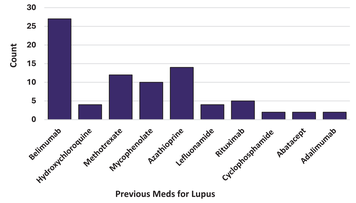

Figure 3: Concomitant Medications for Patients on Anifrolumab

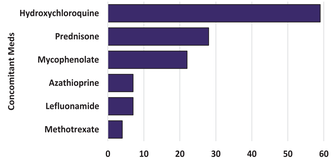

Table 2: Patient Demographics

Patient Demographics	
Gender (n= 116)	
Male	5 (4.3%)
Female	111 (95.6%)
Age Range (years) (n=116)	
18-24	7 (5.9%)
25-34	13 (11.1%)
35-44	25 (21.4%)
45-54	40 (34.2%)
55-64	22 (18.8%)
>65	9 (7.8%)
Switched to anifrolumab from other biologic therapies	
Yes (switched)	63 (53.8)
No (naïve)	54 (46.1)

Results

A total of 116 patients met the inclusion criteria and were evaluated for this retrospective analysis. The study cohort comprised 5 (4.3%) males and 111 (95.6%) females, with an average age of 46 years (range 18-78) *(Table 2)*. Of the 116 patients, 40 (34.5%) discontinued anifrolumab therapy, while 76 (65.5%) remained active. Discontinuation reasons are detailed in Figure 1, with the most common factors being cost and non-compliance, highlighting financial burden and adherence issues as key contributors. Clinical concerns accounted for 21.9% of discontinuations, including adverse reactions (7.3%), contraindications (2.4%), and lack of improvement (2.2%). Other notable reasons included changes in pharmacy providers and patient relocation.

Figure 2 illustrates prior medications in patients who eventually discontinued anifrolumab. Of these, 27 (32.9%) had previously been treated with belimumab, indicating that many patients transitioned from another biologic therapy before starting anifrolumab. Immunosuppressive agents were also commonly used, including azathioprine (17.1%), methotrexate (14.6%), and mycophenolate (12.2%). Less frequently used agents included cyclophosphamide, abatacept, and adalimumab, each reported in 2 patients (2.4%).

Figure 3 summarizes concomitant medications taken while on anifrolumab. Hydroxychloroquine was the most frequently used concomitant medication (59 patients, 46.5%), reflecting its standard role in lupus management. Prednisone or other corticosteroids were used by 28 patients (22%). Immunosuppressive agents were prescribed in 31.4% of cases, with mycophenolate (17.3%) being the most common, followed by azathioprine (5.5%), leflunomide (5.5%), and methotrexate (3.1%).

Discussion

The findings suggest that accessibility improvements and strategies to enhance patient adherence could help reduce discontinuation rates. Addressing provider continuity may also support therapy maintenance. Additionally, the high proportion of patients transitioning from belimumab and other immunosuppressants may suggest that anifrolumab is being prescribed for individuals with more severe or refractory lupus.

The frequent use of hydroxychloroquine and corticosteroids alongside anifrolumab underscores the complexity of disease management and the need for continued efforts to achieve steroid-sparing outcomes. The high number of patients who tried belimumab and subsequently discontinued anifrolumab suggests that some patients may have been resistant to multiple biologic treatments. Patients previously treated with azathioprine, methotrexate, or mycophenolate likely had more severe disease forms. Those coming off cyclophosphamide may have experienced significant disease activity warranting biologic escalation, but discontinuation could reflect issues such as adverse reactions or lack of improvement.

Efforts to improve accessibility and patient adherence could potentially reduce discontinuation rates.

Conclusion

In conclusion, this study contributes to the limited data available on anifrolumab in the home infusion setting. The low discontinuation rate due to ADRs indicates that anifrolumab is generally well-tolerated, in a diverse patient population of patients. The concomitant medications studied in active patients on anifrolumab support SLE remission guidelines (oral corticosteroid (OCS) dose of ≤5 mg per day, stable maintenance doses of immunosuppressants, no use of restricted medicines, and no premature discontinuation of anifrolumab).

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Sara George; Maria Giannakos; Christopher Roy; Veronica Badani: Nothing to disclose.

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